

## REMARKS

This is a response to the Office Action dated January 28, 2005.

### **I. SUMMARY OF OFFICE ACTION**

In the Office Action, numerous objections and rejections made in the July 9, 2004 Office Action were withdrawn in view of Applicants' response filed January 7, 2005. In particular, the objection to Claim 14 was withdrawn. Also, the rejections under 35 U.S.C. § 112, second paragraph were withdrawn. The rejections of Claims 1-3, 5-7, 9-13, and 16 under 35 U.S.C. § 102(b) as being anticipated by Kulys was withdrawn. The rejections of Claims 1-3, 5, 6, 10, 11 and 16 under 35 U.S.C. § 102(b) as being anticipated by Nishizawa was withdrawn but have been rewritten in light of the Applicant's amendment. The rejections of Claims 1-3, 6-12 and 16 under 35 U.S.C. § 102(b) as being anticipated by Castaon were withdrawn. The rejection of Claim 4 under 35 U.S.C. § 103 as being obvious over Nishizawa was withdrawn, but has been rewritten in light of Applicant's amendment.

The Examiner indicated, however, that the Applicant's amendment of January 10, 2005 does not render the application allowable. Further, the Examiner indicated that the Applicant's arguments filed January 10, 2005 have been fully considered but they are not persuasive based on a view that the Examiner disagrees with Applicant's view that Nishizawa does not disclose an ammeter.

The Examiner proceeded to reject Claims 1-3, 5-7, 9-11 and 16 under 35 U.S.C. § 102(b) as being anticipated by Nishizawa, et al. ("Penicillin sensor based on a microarray electrode coated with pH-responsive polypyrrole," hereafter "Nishizawa.").

Claim 4 was also rejected under 35 U.S.C. § 103(a) as being unpatentable over Nishizawa based on a contention that it would have been obvious to one with ordinary skill in the art at the time of the invention to use other enzymes such as those listed in Claim 4, depending on the analyte or interest. Claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Nishizawa in view of Castaon, et al. ("Amperometric detection of ethanol with poly-(o-phenylenediamine)-modified enzyme electrodes," hereafter "Castaon" based on a contention that step c is just a basic step in calibrating an analytical instrument which would have been known to one with ordinary skill in that art of analytical chemistry instrumentation. Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over

Nishizawa in view of Kulys, et al. ("glucose biosensor based on the incorporation of meldola glue and glucose oxidase within carbon paste," hereafter "Kulys.") based on a contention that step b of Claim 13 is just a basic step in calibrating an analytical instrument which would have been known to one with ordinary skill in that art of analytical chemistry instrumentation.

The Examiner noted that Claims 14 and 15 are allowed and that Claims 8 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Examiner also provided a statement of reasons for the indication of allowable subject matter.

## **II. APPLICANTS'S RESPONSE**

### **A. Claims 1-5, 7-10 and 17**

In the Office Action, Claim 1 was rejected under 35 USC Section 102(b) as being anticipated Nishizawa. In response, Applicants have amended Claim 1 to recite "at least one compound, in the form of a monomer, ... " to distinguish the invention recited in Claim 1 over Nishizawa.

In particular, Applicants respectfully submit that Nishizawa as well as Castaon and Kulys do not disclose such limitation. Rather, Nishizawa discloses the use of a polymeric compound (polypyrrole) having pH-sensitive redox properties. Thus, Nishizawa teaches the use of polymers as pH-sensitive redox compound. No substances alternative to polypyrrole are taught or suggested by Nishisawa. The biosensors are clearly said to work on the basis of the specific components. Also, Nishisawa (cf. abstract and penultimate paragraph of page 2642, left col.) teaches the use of a pH-sensitive polypyrrole membrane, / film , pointing at their particular coating function and structure. The obtainment of pyrrole membranes/films is clearly dependent on pyrrole polymerization. Thus, Nishisawa stresses the importance of polymerisation for the pH sensitive substance in view of their essential function of coating element for the biosensor.

Castanon stresses the importance of polymerisation by electropolymerising o-phenyldiammine on the surface of an electrode, and obtaining an electrode coated with a polymeric substance having pH-sensitive redox properties. If the use of isolated monomers

(e.g. o-phenyldiammine) had been envisioned by Castanon, the burdensome step of performing their electropolymerisation would **not** have been taken.

Although one monomeric compound was used by Kulys (Meldola blue), this use was done only in biosensors based on oxidoreductase enzymes limited to detecting oxidisable analytes. The biosensors object of the present claims, however, use enzymes not belonging to the oxidoreductase group, and are suited for the detection of non oxidable analytes. In the biosensors of Kulys type, the analyte is first subjected to oxidation (or reduction) and the electrons involved in this reaction are transferred from the analyte to the working electrode via a sequence of oxidations/reductions; the electron transfer generates an electric current proportional to the concentration of the analyte, and the current is finally read. As indicated on page 5 of the specification, last paragraph, the biosensors according to the present invention work in a completely different manner: in this case the analyte is not subjected to oxidation / reduction, but to a pH-changing reaction, i.e. a reaction generating or consuming hydrogen ions. The resulting shift of pH modifies, in a way proportional to the analyte concentration, the equilibrium between the oxidized and reduced form of a pH-sensitive redox compound. This variation of equilibrium produces an electron current, proportional to the analyte concentration, which is monitored by the ammeter.

Accordingly, for the skilled person it was not obvious to use the monomeric compounds of Kulys into a biosensor working with a very different mechanism of action. Even less obvious was to replace the polymeric membranes/films taught e.g. by Nishisawa with single non-polymerised substances, in the present biosensors.

For the forgoing reasons, Claim 1 is believed to be in condition for allowance. Furthermore, the dependent claims of Claim 1, namely, Claims 2-5, 7-10 and 17 are also believed to be in condition for allowance for being dependent upon an allowable base claim. Also, Claims 2-5, 7-10 and 17 are believed to be in condition for allowance for containing additional patentable subject matter.

B. Claims 14 and 15

The Examiner has indicated that Claims 14 and 15 are allowed.

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### III. CONCLUSION

For the foregoing reasons, Applicants respectfully submit that Claims 1-5, 7-10, 14-15 17 are in condition for allowance. Applicants respectfully submit that all the stated grounds of objection and rejections have been overcome. Accordingly, an early Notice of Allowance is respectfully requested. Should the Examiner have any suggestions for expediting allowance of the application, the Examiner is invited to contact Applicants' representative at the number listed below.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 5/27/05

By:



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